

Conditions for authorisation for supply under regulation 174 of the Human Medicines Regulations 2012 for Ronapreve

General

- This temporary authorisation under regulation 174 of the Human Medicines Regulations 2012 (as amended) (“HMRs”) permits the supply of Ronapreve, based on the safety, quality and efficacy data submitted by Roche Products Limited (“Roche”) to the MHRA from 26 February until 13 August 2021 and until such time as this authorisation is withdrawn.
- This authorisation is not a marketing authorisation for the purposes of Part 5 of the HMRs or Chapter 4 of Title III to Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use.
- This authorisation applies to supply within Northern Ireland.
- As provided in regulation 174A(2) of the HMRs, the sale or supply of the product will not be deemed authorised if the supply is for the purpose of any use other than the recommended or required use, or if a condition in this authorisation is breached (including the conditions of use incorporated into this authorisation).
- Roche is responsible for physically supplying the product in Northern Ireland and for placing the product on the market in Northern Ireland for the purposes of the HMRs, including regulation 345(3).
- Roche is responsible, along with the manufacturers of the product, for the conditions relating to the manufacture of the product and to product release under the terms of this authorisation.
- Roche must operate a comprehensive pharmacovigilance system for the product in accordance with UK legislation for licensed products, as if they were marketing authorisation holders for the product in Northern Ireland, treating the product for pharmacovigilance purposes no differently from how it is treated on the market within Great Britain.
- Roche is not only responsible for compliance with the conditions expressly applied to it in this authorisation, but also, where the conditions apply legislation or guidance that confers responsibilities on marketing authorisation holders, for compliance with any requirement however worded that applies to a marketing authorisation holder in the applied legislation or guidance.

- Any deviations from these conditions can only be made with the prior agreement of the MHRA.
- The MHRA may review and adjust these conditions for temporary supply in response to any developments which it considers material, including any subsequent marketing authorisations that might be issued by other medicines regulators.
- This authorisation will be valid until expressly withdrawn by the MHRA.

Supply in compliance with CMA, quality and distribution

- The supply of Ronapreve is authorised provided that:
 - it complies in all respects with the requirements of the conditional marketing authorisation granted by the MHRA on 19 August 2021 that authorises the sale or supply of the product by Roche in Great Britain, including any variations to that authorisation (“CMA”);
 - without prejudice to the generality of the above, it complies with the differences in quality aspects permitted under a batch-specific variation;
 - any importation or manufacturing facilities located in Northern Ireland are authorised by the MHRA to handle products authorised under regulation 174;
 - all wholesalers and manufacturing licence holders distributing or holding this product are authorised to handle products authorised under regulation 174;
 - all activities are conducted in accordance with Good Manufacturing Practice, Good Distribution Practice and the HMRs (as applicable).
 - notwithstanding Roche’s responsibility for physical supply and placing the product on the market, referred to above, all importers, wholesalers and retailers (including those supplying the product in circumstances corresponding to retail sale) who are responsible, as they will be in the ordinary way, for compliance with the provisions of UK medicines legislation relating to importation, wholesale distribution and final supply that apply to them, comply with those provisions.

Product information and Instructions for Use (PIL and SmPC equivalent)

- Roche must provide product information and instructions for use of the product that are, and continue to be throughout the period of authorisation, identical to the patient information leaflet (PIL) and SmPC that are produced in accordance with the terms of the CMA.
- However, where the CMA is varied under a batch-specific variation to permit deviations from the requirements relating to the PIL and SmPC, the product information and instructions for use under this authorisation may diverge from the PIL and SmPC, provided that they comply with the relevant requirements of the CMA as varied by the batch-specific variation.
- The instructions for use are to be considered as conditions of this authorisation.
- This authorisation does not preclude an authorised prescriber supplying or administering the product to a patient for whom it is not recommended in accordance with the instructions for use, or otherwise than in accordance with the instructions for use, in circumstances where that authorised prescriber is directly responsible for that patient and the supply or administration of the product is to fulfil the special needs of the patient where, in the professional judgement of that authorised prescriber, the welfare of the patient is likely to be in jeopardy unless the product is administered.